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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/21/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/934,249	LEE ET AL.	
	Examin r	Art Unit	
	Zachariah Lucas	1648	

-- Th MAILING DATE of this communication appears on the cov r sh t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8-11,68 and 79-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 8-11, 68, 79-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Claims

1. Currently claims 1-4, 8-11, 68, and 79-88 are pending and under consideration in the application. Claims 1-4, 8-11, 68, and 79-87 were rejected in the prior action, mailed on May 7, 2003. Claims 1, 4, 8, and 80 were amended, and claim 88 was added, in the Response filed on August 11, 2003.

Drawings

2. **(Prior Objection- Withdrawn)** The drawings were objected to as failing to comply with 37 CFR 1.84(p)(5) because they include reference sign(s) not mentioned in the description. In view of the Amendment to the application, the objection is withdrawn.

Claim Objections

3. **(Prior Objection- Withdrawn)** Claims 1 and 4 were objected to in the prior action for including informalities. In view of the amendments to the claims, the objections are withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **(Prior Rejection- Maintained)** Claims 1, 8, and 10 were rejected in the prior action under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant attempted to avoid the rejection of these claims through an amendment that apparently intended to further identify the stringency levels required. However, the claim was drafted such that the actual conditions identified were in a parenthetical statement after mention of the hybridization buffer. It is not clear from the claim whether the parenthetical language is intended as a definition of the stringency conditions, or whether they are merely an example of such conditions.

Further, while the Applicant indicates in the specification that these are high stringency conditions the claim language does not appear to be consistent with what the art considered to be high stringency hybridization conditions. The claim indicates that the high stringency conditions include hybridization in a hybridization buffer at 65° at 3.5 SSC. There are two problems with this. First, the art tends to determine the hybridization conditions by the wash, and not the buffer. See e.g. Kovacs et al., U.S. PGPub 2003/0180728, page 4, paragraphs 0033-0035, and Abo et al., U.S. PGPub 2003/0119146, page 6, paragraph 0047. The claim language does not indicate the wash conditions used, but the actual hybridization conditions of the hybridization assay.

Second, Kovacs also teaches that increased temperature, and decreased salt concentrations are used in higher stringency conditions. As can be seen in the reference, while the Applicant's use of 65 is consistent with these conditions, the Applicant uses both 3.5 SSC and 2.5 Mm NaH2PO4 concentrations, whereas Kovacs indicates that high stringency conditions are achieved at .1 SSC and at .5 Mm NaPO4. Further, the application itself discloses the claimed

conditions as stringent, but not of high stringency. Thus, the claim language does not appear to be consistent with the Applicant's assertion of high stringency. The rejection is therefore maintained against claims 1, 8, 10, and claim 68 as amended for the reasons above, because it is not clear from the claim as to the level of stringency required by the claim, and because the combination of the claim language and the Applicant's arguments do not appear consistent with the art and the specification.

6. **(Prior Rejection-Maintained)** Claims 4, 9, 11, 79-81, and 84- 87 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is also extended to new claim 88, which also reads on the rejected subject matter. Claim 4 will be treated as representative of the rejected claims. This claim reads on isolated nucleic acid molecules consisting of a unique fragment of the sequence of SEQ ID NO: 1, or complements thereto, wherein the fragments includes contiguous nucleotide sequences not identical to any members of a sequence group provided in the claim. The Applicant traverses this rejection on the grounds that one of ordinary skill in the art is expected to be aware of the teachings of the art, and is thus able to determine what sequences are known in the art, and therefore excluded from inclusion as a "unique sequence." This is not found persuasive.

The Applicant contends that it would be clear to one if ordinary skill in the art what fragments fall within the scope of the claim because they would be aware or the fragments known in the art prior to the filing of the present application. While this may be theoretically true, in the present case, the Applicant has made such knowledge essential to understand the

scope of the claims. The material known to the art is necessary for those in the art to determine what the claimed subject matter is unique in comparison to. While the Applicant argues that the claimed fragments are unique with reference to the prior art generally, the Applicant has not provided sufficient information regarding the contents of the prior art for those in the art to determine what fragments of claimed 1 are, in fact, taught by the prior art. By making the teachings of the entirety of the relevant prior art the defining background to the claim, it becomes necessary for the Applicant to demonstrate possession of what is not covered by the prior art. Without such teachings, those in the art would not be clearly appraised of the scope of the "unique fragment' language. The claims are therefore indefinite, and the rejection is maintained over claims 4, 9, 11, 79-81, and 84-88.

7. **(Prior Rejection- Withdrawn)** Claim 68 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the amendment of this claim, further defining the nucleic acid included in the claimed composition, the rejection is withdrawn.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. **(Prior Rejection- Withdrawn)** Claims 1, 2, 3, 8, 10, 82, and 83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In view of the amendment to the claims, the rejection is withdrawn.

10. **(Prior Rejection – Maintained)** Claims 3 and 83 were rejected in the prior action under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For the purposes of this rejection, it is being assumed that the applicant has enabled the use of the full-length protein encoded by SEQ ID NOs: 1 and 3. The rejected claims read on nucleic acids encoding MIVR-1 polypeptides having cardiac cell anti-apoptotic activity. The nucleic acid are described as having either the sequence of SEQ ID NO: 3, or as fragments thereof. The Applicant traverses this rejection on the basis that, having provided the sequence of SEQ ID NO: 3, and methods of identifying fragments with the claimed function, the Applicant has disclosed both the function and the structure of the claimed fragments. This argument is not found persuasive.

While the Applicant may have provided the structure of any fragment of SEQ ID NO: 3, by providing the sequence of SEQ ID NO: 3, the Applicant has not provided any structural characteristics associated with the specific activity being claimed. As was indicated in the prior action, written description support for a genus of DNA molecules requires sufficient disclosure to "define ...structural features commonly possessed by members of the genus [of claimed cDNAs] that distinguish them from others." See, University of California v. Eli Lilly and Co., 43

U.S.P.Q.2d 1398, at 1406 (1997). See also, MPEP § 2163 (stating "The written description requirement for a claimed genus may be satisfied through ...functional characteristics coupled with a known or disclosed correlation between function and structure"). Thus, the Applicant's disclosure of SEQ ID NO: 3, while sufficient to define fragments of SEQ ID NO: 3 generally, is not sufficient structural information to define fragments of the protein with the claimed function because the Applicant has not identified any structural characteristic that is correlated to the claimed function. In view of this, the Applicant's traversal is not found persuasive, and the rejection is maintained.

11. **(Prior Rejection- Maintained)** Claims 1-3, 8, 10, 11, 82, and 83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims read on nucleic acids coding "for a MIVR-1 polypeptide having cardiac cell anti-apoptotic activity." The Applicant traverses this rejection on the grounds that the Examiner has no reason to doubt the anti-apoptotic activity of the identified protein. As indicated in the prior action, those in the art (Tang et al., WO 00/34477, pages 7-8) have identified a protein with about 87% homology to the protein encoded by SEQ ID NO: 3 that is suggested to be a neurotransmitter. Thus, the art clearly provides a reason for those in the art to doubt the asserted activity of the claimed protein. As such, and as the Applicant's sole argument in traversal is an un-supported counter-assertion, the traversal is not found persuasive.

The claims were also rejected because the Applicant had no provided sufficient teachings for those in the art to make or use fragments of the claimed protein that are capable of exerting a cardiac cell anti-apoptotic activity, assuming that the protein itself is enabled. The Applicant traversed this rejection by arguing that no undue experimentation is required to practice the claimed invention, and that the Applicant has provided guidance in the specification that would lead those in the art to the claimed fragments. The Examiner is not persuaded. As indicated by the Applicant, the Court of the Wands case identified a series of factors that may be considered in making an enablement determination. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. The Applicant has identified two factors (identified as 1 and 2 above), and has argued that these factors favor their position.

However, while the Applicant has provided assays that may be performed to identify fragments with the claimed activity, the Applicant has nowhere provide any guidance as to what fragments of portions of the protein encoded by SEQ ID NO: 3 would be capable of performing the claimed function. Thus, the Applicant has not provided guidance to those in the art that would them to the claimed fragments. Rather, they have set forth the assays that may be used to identify such fragments, and left it up to those in the art to determine which, if any , of the protein fragments have the claimed function without guidance. Further, there is no guidance in the art that those attempting to identify such fragments could look to. As described above and in

the prior action, the art relating those proteins with similar structures (sequences) provides no guidance that would be of, and in fact indicate that the protein itself may have an altogether different function from that claimed. Thus, not only is the state of the relevant art rather uninformed, there is little information that those in the art could use to predict what fragments may have the claimed function. Yet, although none of the art, the examples, or the specification provide guidance to identify the claimed fragments, the Applicant is claiming any fragment, of any size, that has the claimed function. In short, with respect to the teachings provided by the Applicant, the claims have a broad scope. Thus, while the quantity of experimentation that may be needed to determine the activity with respect to any one fragment may not be undue, the lack of guidance in the art and the disclosure that could lead those in the art to operable fragments, the breadth of the claims favor a finding of non-enablement. The rejection is therefore maintained for the reasons of record, and the reasons above, against claims 1-3, 8, 10, 11, 82, and 83 and claim 68 as amended.

12. **(Prior Rejection –Maintained)** Claims 4, 9, 11, 79, 80, 81, 84, 85, 86, and 87 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claim read on "unique fragments" of an MIVR-1 nucleic acid sequence. The Applicant traverses this rejection on the grounds that there is no function implied by the "unique" language, that the disclosure of SEQ ID NO: 1 is sufficient to characterize the unique fragments thereof, and that fact that SEQ ID NO: 1 shares homology to certain other known

proteins is not relevant to the claimed invention. The traversals are not found persuasive, and the rejection is therefore maintained.

The Applicant's disagreement with the Examiners classification of the definition of the fragments as comprising a functional element is noted. However, this disagreement is not deemed dispositive of the issue. Regardless of whether properties by which the claimed fragments are defined are considered to be functional, the Applicant has not provided any examples or description of the claimed fragments other than the presence of these properties. There is no structural information disclosed in the application to show that the Applicant was in possession of the claimed fragments as opposed to any fragment. Because the application lacks any description of the claimed fragments other than the desired non-structural traits, the application lacks descriptive support for the claimed genus.

The disclosure of SEQ ID NO: 1 is not, alone, sufficient information to describe the unique fragments because the Applicant is not claiming any fragment of the sequence, but only fragments with specific properties- signatures and not known in the prior art. As indicated in the prior action, these unique fragments are merely described as being capable of acting as a signature for the identified sequence, and as not known in the prior art. The Applicant has neither provided a synopsis of the prior art such that those in the art have been apprised of what sequences are excluded by this aspect of the claimed fragments, nor provided any examples or identification of the "unique fragments." Thus, the Applicant has provided no structural information by which one of ordinary skill in the art could distinguish the unique fragments from other fragments of SEQ ID NO: 1. While SEQ ID NO: 1 may be representative of the genus of any fragment, because it does not itself have the properties of being a "unique fragment" of

itself, it is not a representative example of the claimed genus to show the Applicant's possession of the genus. As the Applicant has not provided any examples or description, other than disclosure of the whole of SEQ ID NO: 1, of the fragments, the Applicant has not provided adequate written description support for the claimed genus of inventions. The rejection is therefore maintained against claims 4, 9, 11, 79, 80, 81, 84, 85, 86, 87, and new claim 88.

Claim Rejections - 35 USC § 102

13. **(Prior Rejection-Maintained)** Claim 1 was rejected in the prior action under 35 U.S.C. 102(a) as being anticipated by either Tang et al. WO 00/34477, or by Xu et al., Genomics 66:257-63 (June 2000, Accession number AF224278). While the Applicant has amended the claim, and traversed the rejection as it applies to the amended claim, the traversal is not found persuasive. This is because the Examiner does not agree that the Applicant has appropriately indicated the use of a high stringency solution with regards to the hybridization conditions as indicated above.

Conclusion

14. No claims are allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
October 20, 2003

JAMES HOUSEL 10/20/03
SUPERVISORY PATENT EXAMINER
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